UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,689	12/08/2003	Todd K. Whitehurst	AB-311U	5724

23845 7590 11/15/2006

ADVANCED BIONICS CORPORATION
25129 RYE CANYON ROAD
VALENCIA, CA 91355

EXAMINER	
BERTRAM, ERIC D	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/730,689	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Eric D. Bertram	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 9/8/2006 have been fully considered but they are not persuasive. The Applicant argues that there is no teaching or suggestion in any of the prior art of record of implanting a stimulator within a patient's spinal column. Specifically, the Applicant claims that King teaches away from this by teaching that only a lead is placed in the spinal column. The Examiner respectfully disagrees. Nowhere does King explicitly state that a stimulator should not be placed in the spinal column. As noted by the Applicant (page 9 of the response), King does teach, however, that the electrodes may be placed in the spinal column in order to achieve effective spinal cord stimulation. While Schulman does not teach placing the microstimulator in the spinal column, it is of a size and shape suitable for placement in the spinal column. Furthermore, the microstimulator of Schulman has electrodes 14 and 15 that are connected to the stimulator circuitry as shown in figure 4. Therefore, if one were to implant the electrodes of Schulman in the spinal column, as explicitly taught by King, then the stimulator is inherently implanted in the spinal column as well since it is the same structure. As a result, the 35 USC 103(a) rejection of claims 1-4 and 7-11 are still considered proper.

2. The Applicant further argues that while ischemia of the heart may be related to angina, the two are not synonymous. However, the Applicant is directed to the attached Wikipedia article on angina, which states in the first line that "Angina pectoris is chest pain due to ischemia...of the heart muscle." Therefore, angina and ischemia, while not

synonymous by definition, are inherently tied together such that if ischemia is not present, angina cannot be present either. The Applicant further argues that King only teaches a method of treating limb ischemia and does not teach treating ischemia of the heart. Again, the Examiner respectfully disagrees. King specifically states that procedure may be utilized to improve blood flow in other parts of the body, including human organs, of which the heart is inherently included (Col. 7, lines 50-53). Furthermore, King teaches that the electrodes should be placed at optimal spinal cord locations that project to the specific organ desired to be treated (Col. 11, lines 34-39). Therefore, King does teach a method for treating ischemia of all organs, including the heart, and the 35 USC 103(a) rejections of claims 12, 15 and 18-20 are still considered proper.

3. Regarding claims 5, 6 and 16, the Applicant merely relied on the arguments presented against King, Dooley and Schulman, as discussed above. As such, the 35 USC 103(a) rejections of these claims are still considered proper.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-9, 11 and 13-17 of copending Application No. 10/731,551 in view of Rise (US 5,824,021). The copending application discloses the basic method of implanting a stimulator near nerves in order to treat angina of a patient. The copending application does not specifically disclose implanting the stimulator within the spinal column in order to stimulate nerves of the patient. Attention is directed to the secondary reference of Rise, which teaches implanting a stimulator wholly with the spinal column in order to stimulate nerves for the treatment of angina (see figure 2 and Col. 2, lines 19-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the copending application by implanting a stimulator in the spinal column as taught by Rise in order to specifically stimulate nerves for the treatment of angina (Col. 1, lines 29-32).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-12, 15 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over King (US 6,058,331) in view of Dooley et al. (Modification of Blood flow to the extremities by electrical stimulation of the nervous system, hereinafter Dooley) and further in view of Schulman et al. (US 5,193,540, hereinafter Schulman). King discloses a method for treating a patient with peripheral vascular disease (PVD) and angina (i.e. ischemia of the heart). King describes implanting a stimulator,

comprising lead 18 and signal generator 14, with at least one electrode within the spinal column of a patient in order to stimulate tissues that influence blood circulation (Col. 5, lines 2-30). Operating power is delivered to the stimulator by signal generator 14, which also receives stimulation parameters transmitted from external component 20 (Col. 4, lines 45-51). The pulse generator then generates stimulation pulses in accordance with the received parameters and delivers the pulses via the lead to the tissues that influence blood circulation. King discloses that the tissue may be a peripheral nerve from the spinal cord (Col. 5, line 1), which includes the spinal roots. However, since King does not specifically disclose the stimulation of the spinal roots, attention is directed to the secondary reference of Dooley, which discloses the electrical stimulation of the peripheral nerves, and specifically the spinal roots, in order to improve blood flow to different parts of the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method King by specifically stimulating the spinal roots as taught by Dooley, since Dooley discloses that patients with spinal root stimulation had significant arterial dilation in the extremities.

10. King, as described above, discloses the applicant's basic invention with the exception of using a stimulator that is entirely implantable within the spinal column of a patient. Attention is directed to the reference of Schulman, which discloses a miniature implantable stimulator (see figure 4). The stimulator is of such a size and shape (2mm x 10mm) that it is suitable for placement entirely within the spinal column of a patient by using a hypodermic needle (Col. 3, lines 53-68). Once the stimulator is implanted near the spinal roots, as taught by King and Dooley above, operating power and stimulation

parameters are provided to the stimulator using transcutaneous transmission with external appliance 6, as shown in figure 2 (Col. 4, lines 36-51). The stimulator then generates pulses in accordance with the received parameters and delivers the pulses to the adjacent tissue by electrodes 14 and 15 (Col. 4, line 61-Col. 5, line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to substitute the stimulator of Schulman for the stimulator system of King, since they perform the same functions, and the stimulator of Schulman is less invasive and thus safer for use in the patient.

11. Regarding claims 2, 3 and 25, King discloses stimulating the lumbar area for treatment of PVD in a lower limb and stimulating the cervical area for treatment of PVD/ischemia in the upper body of a patient (Col. 5, lines 15-30).

12. Regarding claims 7-11 and 18-20, King discloses using a sensor 30 for monitoring the physical condition of the patient (Col. 5, lines 63-66). The sensed condition is then sent to the external component 20, which processes the signal from the sensor to adjust the stimulation parameters (Col. 4, lines 48-51). Alternatively, the sensor may send the signal directly to the stimulator, and the stimulator may internally adjust the stimulation parameters (Col. 6, lines 6-18).

13. Regarding claims 17 and 21-23, King does not expressly disclose using stimulation pulses with an amplitude less than 15 mA or a frequency less than 100 Hz. However, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use stimulation pulses with an amplitude less than 15 mA or a frequency less than 100 Hz since it has been held that, where the general conditions of

a claim are disclosed in the prior art, discovering an optimum value or range for a result effective variable involves only routine skill in the art (see MPEP 2144.05).

14. Regarding claim 24, King discloses placing a sensor near the dorsal roots (Col. 6, lines 51-53)

15. Claims 5, 6, 13, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Dooley and Schulman and further in view of Rise (US 5,824,021). King, as described and modified above, discloses the applicant's basic invention, including stimulating the patient's spinal roots in order to increase blood circulation to organs of the body experiencing ischemia, which would include angina. However, since King never specifically discloses the treatment of angina; attention is directed to the reference of Rise, which discloses delivering stimulation pulses to the thoracic area of the vertebrae as a treatment for angina (Col. 2, lines 27-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method King by specifically stimulating the thoracic area of the vertebrae as treatment for angina as taught by Rise since this area will specifically increase coronary blood circulation in a patient (Col. 1, lines 29-32)

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EDB